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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,895	03/04/2004	Christian Keller	7346	5189

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EXAMINER	
SINGH, JASVEER	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,895	KELLER ET AL.	
	Examiner	Art Unit	
	Jasveer Singh	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *3,5,6,13,18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-12,14-17,19,22 and 23* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

During a telephone conversation with Terrence Brown on September 6, 2006, a provisional election was made without traverse to prosecute the invention of claims 1, 2, 4, 7-12, 14-17, 19, 22 and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 5, 6, 13, 18, 20 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 2 is objected to because of the following informalities: "in" should be "is". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

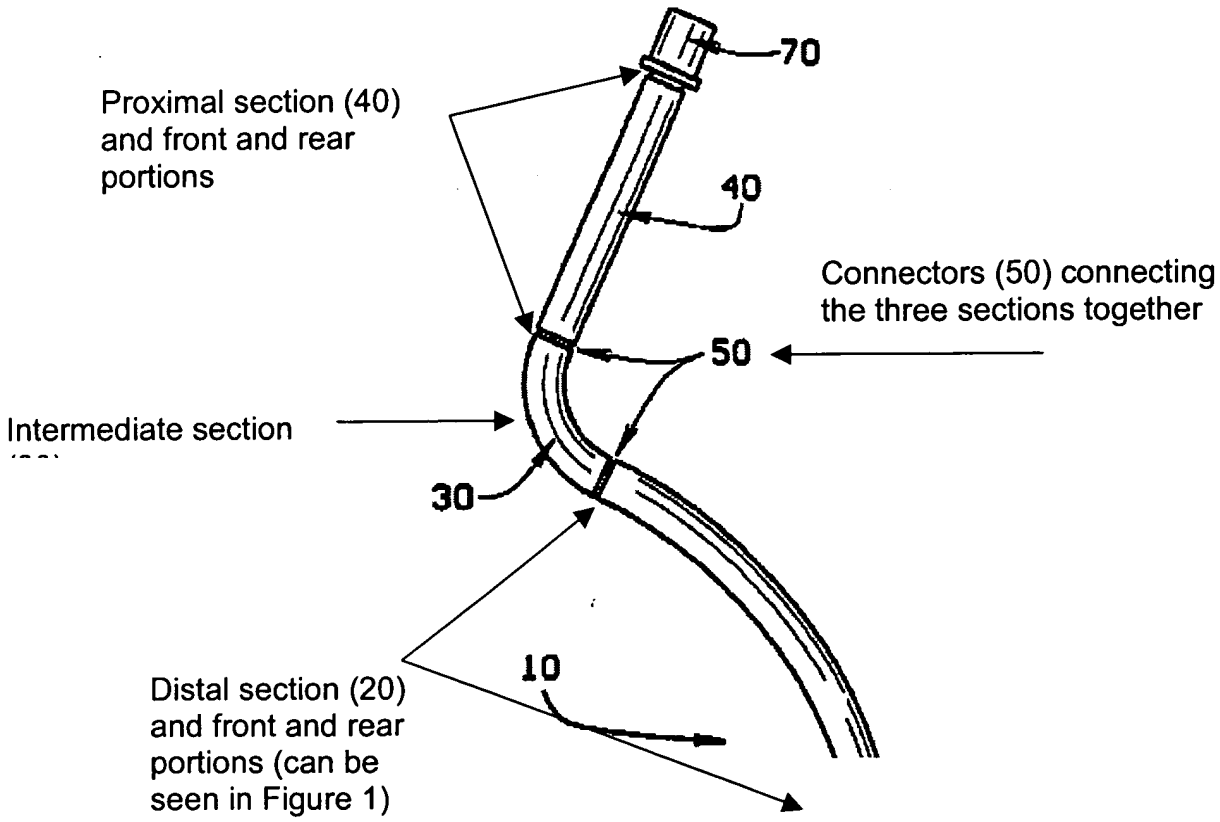
Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Virag et al (US 5,546,936) in view of Brain (US 6,055,984) and in view of Merideth (US 6,164,277). Virag et al in a Tracheal Tube With Reinforced Flexible Segment discloses:

- A slender insert (10) (Figure 1) wherein the "length of the tracheal tube will vary in accordance with the needs of a particular patient" and wherein "several standard length and shapes may be provided wherein the lengths are chosen so as to conform as closely as possible to the shape of the posterior pharynx and

trachea of a patient and the shape is chosen so as to allow for either nasal or oral intubation" (Detailed Description of the Invention, Column 5, Lines 11-20).

Thus, Virag et al. meet the limitation of the slender insert's length as the limitation states that the length depends on the patient's size.

- Insert (10) having proximal (40), intermediate (30), and distal (20) sections integrally connected by connectors (50), where one connector connects the proximal section (40) to the intermediate section (30) and the other connects the distal section (20) to the intermediate section (30).
- Proximal section (40) and distal section (20) having front and rear portions, as shown below:



- With regards to the distal section front portion extending from about 0.5% to about 50% of the total length of said slender insert (10), the applicant has not disclosed that this specificity implies any particular criticality or useful advantage.

  Further, Virag et al. do not disclose a specific length or range of lengths for the distal section (20) with respect to the total length of the insert (10) however do disclose that the "length of the tracheal tube will vary in accordance with the needs of a particular patient" and "several standard length and shapes may be provided wherein the lengths are chosen so as to conform as closely as possible to the shape of the posterior pharynx and trachea of a patient and the shape is chosen so as to allow for either nasal or oral intubation" (Detailed Description of the Invention, Column 5, Lines 11-20).

  Therefore it would have been obvious to one of ordinary skill in the art to make the distal section front portion in accordance with the needs of a particular patient as such would have been a matter of engineering design choice.

- Distal section (20) front portion having an end tip (60)
- Distal section (20) comprising a soft, malleable and ductile material extending from said distal section (20) front portion end tip (60) through said distal section (20) rear portion. Virag et al disclose that:

"the distal end portion (20) and the proximal end portion (40), of tracheal tube 10, may be preformed from any suitable material having sufficient memory or resilience to return to the preformed shape following flexure. In particular, the distal end portion (20), should be made of a material which enables it to conform to the posterior pharynx and trachea of the patient, rather than forcing the posterior pharynx and trachea to conform to the tracheal tube...Flexible thermoplastic materials such as polyvinylchloride, polyethylene, or the like are preferred materials meeting all of the above requirements" (Detailed Description of the Invention, Column 6, Lines 6-19).

The preceding text taken from Virag et al implies that the material be soft, malleable and ductile and, therefore, the claim limitations are met by Virag et al.

- Intermediate section (30) comprising a stiff, malleable and ductile material stiffer than said soft malleable and ductile distal section and having a selected hardness of between about 50 SHORE A to about 90 SHORE D. Virag et al disclose that:

"flexible portion (30) may be formed of any suitable flexible material which allows for acute bends while maintaining constant connection to other portions of the tracheal tube (10). This material must be capable of such bends without kinking of transferring unnecessary force to the proximal end portion (4), or the distal end portion (20), while maintaining constant inside and outside diameters. In a preferred embodiment, flexible portion (30) is formed from either expanded polytetrafluoroethylene (PTFE) tubing or a polyethylene material (any grade). Such a material is useful for forming a non-reinforced flexible tube" (Detailed Description of the Invention, Column 6, Lines 23-35).

Therefore Virag meets the limitation of the intermediate section (30) being stiffer than the distal section (20). With regard to the limitation of the intermediate section (30) having a selected hardness of between about 50 SHORE A to about 90 SHORE D, the shore hardness D of PTFE was found to be 55-72, and therefore Virag's PTFE lies within the range of the claim limitation (See www.elringklinger-kunststoff.de/pages/e_werkst_elring_ptfe.html).

- Distal section (20) having a SHORE hardness approximately 20% to approximately 30% less than said selected hardness of said intermediate section. It is obvious that the material for the distal section (20) would have a lower SHORE hardness than the material for the intermediate section (30) since it is less stiff and hence less hard as well. Further, applicant has not disclosed criticality or particular advantage for the shore hardness to hold those exact values, and has not disclosed a disadvantage for the shore hardness to hold values other than the claimed.

As to claim 2, Virag et al disclose wherein the said slender insert is a tube (10)

As to claim 4, Virag et al disclose wherein the said distal section (20) SHORE hardness is constant from said distal section (20) front portion end tip (60) through said distal section (20) rear portion. Virag does not disclose a change in SHORE hardness throughout the distal section (20) so it is therefore constant.

As to claim 7, Virag et al disclose the claimed invention with the exception of the slender insert (10) being opaque. Brain in an endotracheal tube construction teaches

a radio-opaque filler for greater radiation-viewing of an endotracheal tube position in the patient's anatomy (Detailed Description of the Invention, Column 6, Lines 2-8). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify invention of Virag et al to include the Radio-opaque filler as taught by Smith to provide greater radiation-viewing of an endotracheal tube position in the patient's anatomy.

As to claim 8, Virag discloses wherein the slender insert (10) includes a fiber optic means. "A further advantage of the tracheal tube according to the present invention is the provision of a smooth constant diameter lumen throughout the length of the tracheal tube. This construction allows for ease of passage of instruments, such as, fiber optic scopes and suction catheters, for example, through the tracheal tube" (Detailed Description of the Invention, Column 8, Lines 1-9). Therefore Virag meets the limitations of the claim.

As to claim 9, Virag et al disclose wherein the slender insert (10) is made of plastic. Virag et al disclose, as seen in the rejection of claim 1, that the insert can be made of polyethylene, which is a type of plastic. Therefore Virag et al meet the limitations of the claim.

As to claim 10, Virag et al discloses wherein the slender insert (10) is made of polyethylene, as seen in the claim 9 rejection.

As to claims 11 and 12, Virag discloses the claimed invention except for an insertion depth indicating means that includes measuring indicia. Merideth in an intubation stylet teaches measuring indicia (34) which may be included on the outer

diameter of guide member (12). The indicia (34) indicate the approximate insertion depth of the distal end 18 (See Figure 2).

Therefore it would have been obvious to one of ordinary skill in the art to modify the measuring indicia as the insertion depth means as taught by Merideth in order to indicate the approximate insertion depth.

As to claim 14, Virag et al disclose the claimed invention except for the proximal section extending from about 0.5% to about 20% of the total length of said slender insert (10). However, applicant has not disclosed a criticality or particular advantage for this specific range. Therefore it would be obvious to select any range so long as it would be compatible with the anatomy of a patient.

As to claim 15, Virag et al disclose wherein the said proximal section (40) front portion has an end tip. "The proximal end portion (40) comprises a relatively straight segment of tubing which terminates in an inlet orifice adapted to receive a standard connector" (Detailed Description of the Invention, Column 5, Lines 20-25). A tip is defined as "2: a small piece or part serving as an end, cap, or point" (m-w.com). Since the inlet orifice of Virag is a part serving as an end, Virag et al meet the limitations of the claim.

As to claim 16, please note the rejection of claim 1. Virag et al disclose that what applies to the distal end applies to the proximal end as well, as seen in the supporting citation in the claim 1 rejection.

As to claim 17, please note the rejection of claim 2.

As to claim 19, please note the rejection of claim 4. Virag et al disclose that what applies to the distal end applies to the proximal end as well, as seen in the supporting citation in the claim 1 rejection.

As to claim 22, Virag et al disclose the claimed invention except for the proximal section being bent at an angle of about 25 degrees to about 45 degrees with respect to said intermediate section. However, applicant has not disclosed any criticality or useful advantage for this exactness in the claim. Therefore it would have been obvious to use any angle, so long as it is accordingly set to the demands of a patient's anatomical structure.

As to claim 23, please note the above rejection of claim 22.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The considered pieces of prior art have been listed on the PTO-892 form which is attached.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jasveer Singh whose telephone number is (571) 272-5508. The examiner can normally be reached on M-F (9am - 6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jasveer Singh
Patent Examiner in Art Unit 3743
September 6, 2006

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